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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/988,496	11/20/2001	David J. Anderson	CTCH-P01-007	8536

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ROPES & GRAY LLP  
ONE INTERNATIONAL PLACE  
BOSTON, MA 02110-2624

EXAMINER

SHUKLA, RAM R

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 08/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/988,496

**Applicant(s)**

ANDERSON ET AL.

**Examiner**

Ram R. Shukla

**Art Unit**

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-72 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-72 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

1. Claims 1-72 are pending.

***Election/Restrictions***

2. Restriction to one of the following inventions is required under 35 U.S.C.

121:

- I. Claims 1-9, drawn to a method of delivering an agent to arterial smooth muscle cells in a mammal, classified in class 514, subclass 1.
- II. Claims 10-25, drawn to a transgenic animal comprising an indicator gene and a method of using the animal, classified in class 800, subclass 3.
- III. Claims 26-31, drawn to a method of identifying an arterial smooth muscle cell in a tissue sample from a mammal, classified in class 435, subclass 4.
- IV. Claims 32-38, 40, drawn to a method of isolating an arterial smooth muscle cell from a tissue sample from a mammal and the isolated cell, classified in class 435, subclass 325.
- V. Claim 39, drawn to a method of screening for compounds that affect an arterial smooth muscle cell, classified in class 435, subclass 6.
- VI. Claim 41, drawn to a cDNA library produced from an arterial smooth muscle cell, classified in class 536, subclass 23.1.
- VII. Claim 42-44, drawn to an oligonucleotide encoding a targeting molecule, classified in class 435, subclass 320.1.
- VIII. Claims 45-48 and 60-64, drawn to a method of inducing expression of a polypeptide in arterial smooth muscle cells of a mammal, classified in class 514, subclass 44.
- IX. Claims 49-51, drawn to an ex vivo method of modifying arteries in a mammal by introducing arterial smooth muscles cells into the mammal, classified in class 424, subclass 93.1.

- X. Claims 52-59, drawn to a method of modulating angiogenesis in a mammal by administering a composition comprising an agent and a substance that binds to EphrinB2, classified in class 424, subclass 1.
- XI. Claims 65-70, drawn to a method of modulating angiogenesis in a mammal by administering to the mammal a substance that binds to EphrinB2, classified in class 424, subclass 1.
- XII. Claim 71, drawn to a composition of an artificially prepared vessel comprising arterial smooth muscle cell that comprise a recombinant nucleic acid that increases the expression of the endogenous EphrinB2, classified in class 435, subclass 325.
- XIII. Claim 72, drawn to a method of diagnosing the presence of a tumor in a mammal by detecting the expression of EphrinB2 in blood vessels of the mammal, classified in class 435, subclass 6.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions of the groups I, III, IV, V, VIII-XI and XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods that have steps that are distinct to each method and cannot be interchangeably used among the methods. For example, the steps of a methods of delivering an agent to a smooth muscle cell (group I) can not be used for identifying a an arterial muscle in a cell (group III) or isolating smooth muscle cells (group IV) or for screening of a compound (group V) or a method of gene therapy in an animal in vivo or ex vivo (groups VIII and XI) or the steps of a method of modulating angiogenesis in group VIII-XI. Additionally, different methods will require distinct compositions for practice and will result in the production of distinct compositions. For example, the invention of group VIII requires a nucleic acid whereas the invention of group X requires combination of an agent and a substance or the invention of group X requires only a substance that

binds EphrinB2 and the invention of group IX requires a cell composition. All these compositions have different structure and function and search for one will not be coextensive with the other.

Inventions of the groups II, VI, VII and XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions are drawn to different compositions that have distinct structure and functions and have different utilities. For example, the structure of an animal is different from that of a cDNA library or a nucleic acid expression construct. Additionally, the utilities of a cDNA library are different from that of a nucleic acid expression construct or a transgenic animal. Likewise the structure, function and utilities of the cells vessels of group XIII are distinct from those of a cDNA library or nucleic acid construct or transgenic animal.

The compositions of each of the groups II, VI, VII and XIII are patentably distinct from the methods of each of the groups I, III, IV, V, VIII-XI because the claimed methods cannot be used for making the compositions. Alternately, the compositions cannot be used in practicing the methods. Therefore, the inventions of the groups I-IX will require separate and distinct searches in the patent and non-patent literature.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art shown by their different classification and their recognized divergent subject matter, and because each invention requires a separate, non-coextensive search, restriction for examination purposes as indicated is proper.

4. This application contains claims directed to the following patentably distinct species of the claimed invention: Claims 8, 44, 46, 51, and 64 recite several distinct species.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic

claim is finally held to be allowable. Currently, claims 8, 44, 46, 51, and 64 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

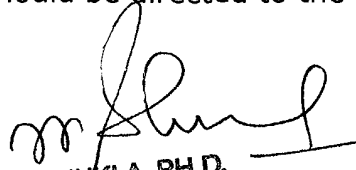
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is

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(703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for TC 1600 is (703) 703-872-9306. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the William Phillips whose telephone number is (703) 305-3413.

  
**RAM R. SHUKLA, PH.D.**  
**PRIMARY EXAMINER**

Ram R. Shukla, Ph.D.  
Primary Examiner  
Art Unit 1632